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TITLE: Evaluating a Novel Sleep-Focused Mind-Body Rehabilitative Program for Veterans with mTBI and Other Polytrauma Symptoms: An RCT Study

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14. ABSTRACT Subjects are being recruited for the proposed study and the study is still ongoing. There is no finding to report from the study as of 30/09/2014.					
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Annual Report

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4. Introduction

The purpose of the study is to evaluate and compare the clinical benefit of two sleep-focused therapeutic interventions: Mind-Body Bridging (MBB) and Supportive Education (SED) on sleep and comorbid mild Traumatic Brain Injury (mTBI) symptoms. We will recruit 142 OEF/OIF veterans with mTBI, who first will undergo a comprehensive evaluation performed by our medical and psychological staff, and then will be assigned to one of the two programs (MBB or SED). Each veteran will receive a total of 6 hours of sleep-focused treatment, in 2-hour sessions once a week over 3 consecutive weeks. Each patient will be evaluated again after treatment has ended. Three months after treatment ends, patients will have another evaluation. Six months after treatment ends, patients will complete follow-up questionnaires. These assessments will help us to evaluate both the efficacy of the therapy programs and document any differences in individual treatment response. Additionally, the project will explore underlying mechanisms of action involved in treatment benefits resulting from MBB and SED by using a biomarker of stress as a proxy indicator of intermediate mechanisms activated by MBB and SED.

5. Body

We hired psychologists to do psychological evaluation, a Physician Assistant to do physical evaluation and LCSWs to do interventions.

We hired a research assistant.

We started recruitment. We screen the patients lists obtained from Polytrauma Clinic at VA, send recruitment letters and make phone calls to follow-up with the letters we sent.

The list was smaller than we expected to have a large number of subjects for the study during the shorter time period. This may mean that the study may take longer than it was originally projected to last. We are currently exploring more options for recruitment.

We will post flyers and brochures at Salt Lake VA and other approved locations, and distribute study information to OEF/OIF resource groups.

First intervention groups started in April and the participants who completed the groups also completed the post-intervention evaluation and 3 month follow-up evaluation.

Second intervention groups are scheduled to start in October.

6. Key Research Accomplishments

- Hired Psychologists, LCSWs and Physician Assistants
- Started recruitment
- Completed first intervention groups and post and 3 month evaluations for those who completed the intervention
- 13 Veterans consented to participated in the study
- 2 Veterans completed intervention sessions
- 2 Veterans completed post-intervention and 3 month follow-up evaluation
- Setting up online survey (REDCap)

7. Reportable Outcomes

Study enrollment is still currently ongoing. We do not have any result yet to report here.

8. Conclusions

Study enrollment has started during Year 2. We are currently not in a position to reach any conclusion regarding study aims and hypothesized benefits of the experimental intervention program (MBB) at the end of Year 2.

9. References

None

10. Appendices

None

11. Supporting Data

None